RealSeal™ Endodontic Obturation System (Project 04-32) (4/05)

RealSeal™ is a synthetic polyester endodontic obturation material that contains bioactive and radiopaque fillers. RealSeal™ reportedly demonstrates all the advantages of gutta-percha (e.g., radiopacity, biocompatibility, retrievability, insolubility, thermoplasticity) plus the potential added advantages of reduced microleakage and increased strength. The sealer is a dual-cured resin-based composite with fillers of calcium hydroxide, barium sulfate, barium glass, and silica. The obturation material purportedly forms a "mono-block" or continuous bond between the canal wall, sealer, and cones, providing a reported improvement in sealing and root strengthening. Because RealSeal™ is designed like gutta-percha systems (e.g., master and accessory cones), it reportedly has a minimal learning curve.

Manufacturer:
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Suggested Retail Price:
$159.00 Intro Kit (item number 972-2100)
- 0.04 taper #15 – #40 points (20/per size)
- 0.06 taper #15 – #40 points (20/per size)
- Root Canal Sealant (with 12 mixers)
- 3-mL bottle Thinning Resin
- 6-mL bottle Primer
- mixing wells (25)
- applicator brushes (25)

Government Price:
$95.00 Intro Kit (item number and contents as listed above)

ADVANTAGES:
+ Designed like gutta percha for ease of use and reduced learning curve
+ Highly radiopaque
+ Potential reduction in microleakage
+ May potentially improve fracture resistance
+ Eugenol free
+ Retrievable
+ Immediate coronal seal when light cured

DISADVANTAGES:
- Small sealer syringe with potential waste with mixing tips
- Microbrushes may be too large
- Basic kits lack pellets for warm gutta-percha backfill
- Lacks larger cone sizes in larger taper systems
- Sealer may be more expensive than traditional ZOE systems
- More time consuming with additional steps
- Relatively sticky when heated
- No clinical studies

SUMMARY AND CONCLUSIONS:
RealSeal™ is a new radiopaque endodontic obturation material based on Resilon, a thermoplastic synthetic polymer-based root canal filling material. Similar to gutta percha, there are master and accessory cones in ISO (International Organization for Standardization) sizes. However, clinical evaluators noted a lack of larger cone sizes for systems of greater taper (i.e., 0.04, 0.06). Pellets may be purchased separately, which can be used for backfill in the warm thermoplasticized technique. The sealer is a dual-cured dental composite resin sealer. Forty seconds of light will cure the coronal 2 mm of the canal, whereas the entire filling will self-cure in approximately 15 to 30 minutes. Some evaluators felt the sealer syringe was small and wasteful. Also, the price of RealSeal™ sealer, primer, and thinner resin may be more expensive than traditional zinc oxide and eugenol sealers. All of the clinical-users rated RealSeal™ as "excellent" or "good" overall and most would consider purchasing it for use in their practice. Published laboratory studies suggest that RealSeal™ may improve fracture resistance and reduce microleakage compared with gutta percha.[1,2] Long-term clinical studies are necessary to substantiate the potentially improved performance of this new material. **RealSeal™** is rated **Acceptable** for use in USAF dental facilities.

References
1. Teixeira FB, Teixeira EC, Thompson JY, Trope M. Fracture resistance of roots endodontically treated with a new resin filling material. J Am Dent Assoc 2004;135:646-652.
2. Shipper G, Orstavik D, Teixeira FB, Trope M. An evaluation of microbial leakage in roots filled with a thermoplastic synthetic polymer-based root canal filling material (Resilon). J Endod 2004;30:342-347.

UPDATE

The original formulation of Resilon-based obturation materials (e.g., Epiphany, Pentron; RealSeal, SDS) utilized a water-soluble red dye that under certain conditions may leach out into the tooth and turn the tooth pink. The dye is reportedly a harmless FDA-approved food-grade dye. The company claims that only a few clinical cases have been reported. Resilon-based obturation systems are now produced with insoluble pigment to purportedly prevent this effect. The potential for discoloration reportedly only exists for the originally produced batches of Resilon material.